UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, *et al.*, *ex rel.* JULIANNE NUNNELLY and MATTHEW SHANKS

Plaintiffs,

v.

REGENERON PHARMACEUTICALS, INC.,

Defendant.

1:20-cv-11401-PBS

Leave to file granted on 06/07/2024

DEFENDANT REGENERON'S REPLY
IN SUPPORT OF ITS MOTION TO DISMISS

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PRELIMINARY STATEMENT

The basic question in this case is whether Regeneron complied with the terms of a statute, namely 42 U.S.C. § 1395w-3a(c)(3). Yet that statute barely makes a cameo in Plaintiffs' brief—likely because its text confirms that Regeneron is in full compliance. Congress was explicit: "In calculating the manufacturer's average sales price" of a drug, manufacturers "shall include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates." Plaintiffs do not seriously claim that Regeneron failed to include any of those enumerated discounts in calculating EYLEA's ASP. While they briefly and obliquely argue that Regeneron provided a "rebate" by allowing customers to buy EYLEA with a credit card without incurring any processing fees, they quickly pivot away from that theory. And for multiple good reasons: Not only is using a credit card sans surcharge to cover processing fees the default mode of payment throughout our economy, but Plaintiffs expressly disclaim that the physicians' cash back or credit card rewards is a "rebate." Instead, they assail Regeneron's reimbursement to distributors for transaction fees actually incurred. But reimbursing expenses actually incurred by merchants (here, distributors) is not a "rebate" to consumers (here, doctors). If Congress wants the cost of processing credit card transactions to be included in ASP, it can amend the statute. But DOJ cannot use FCA litigation to evade bicameralism and presentment.

That leaves DOJ and the intervening states arguing that Regeneron was required to include in (i.e., subtract from) EYLEA's ASP anything they (now) say is a "price concession," whether or not it made Congress' list. That argument would not fly even in *Chevron*'s heyday, and it is a non-starter today. To be sure, Congress delegated authority to "the Secretary [of HHS]" to require manufacturers to "include in [ASP] other price concessions … that would result in a reduction of the cost to the purchaser." But DOJ is not HHS—and, more important, HHS has not exercised that authority to add anything to Congress' list. The only thing HHS has actually done is parrot

Congress' enumerated list and then clarify that bona fide service fees may be excluded from ASP. If HHS wanted manufacturers to include the reimbursement of something that to all the world looks like a bona fide service fee, it needed to say so expressly. Instead, it said the opposite, clarifying that "bona fide service fees" may be excluded, even if they arguably look like chargebacks, rebates, or any of the other types of price concessions enumerated in the text.

That regulatory intervention doubly defeats Plaintiffs' claims, since financial institutions plainly perform a bona fide service when they process credit card transactions. Indeed, Plaintiffs never deny that. They instead claim that the real "'service'" here is "providing a lower price to Eylea customers." Opp'n 32. That is word play, not a serious argument. All bona fide service fees cover services that benefit physicians, and theoretically could be charged to them. Physicians might pay extra for shipping, if it were not included, and thus benefit when distributors do not surcharge for it because they are reimbursed for the actual costs of the service by the manufacturer. Yet, the government has never attempted to (re)characterize that arrangement as lowering the effective price for physicians who get the benefit of included shipping; it instead treats shipping as a prototypical bona fide service. There is no material difference when distributors refrain from surcharging for credit card transaction fees, and the manufacturer reimburses them for fees actually incurred. While doctors may not get cashback from FedEx, Regeneron cannot be faulted—let alone be subjected to massive FCA liability—for the credit card companies' distinct business model, especially when DOJ (rightly) disclaims treating the cashback and rewards as a rebate.

The problems with Plaintiffs' claims do not end there. As a nod to its own lack of clear guidance and the unfairness of imposing massive liability on manufacturers for guessing wrong about matters the government has purposefully left opaque, HHS requires only reasonable judgments in calculating ASP. Yet *Plaintiffs never argue that Regeneron's interpretation is*

unreasonable. Plaintiffs also conveniently ignore the many industry requests for guidance, that CMS acknowledged the lack of clarity but declined to offer any, and that HHS-OIG took pains to underscore the need for additional guidance. *See* MTD 8-9. Plaintiffs' silence speaks volumes.

Plaintiffs also fail to allege anything actually false in any actual claim for payment—a basic requirement under the FCA following the 2009 amendments. Plaintiffs invoke cases excusing that requirement, including this Court's decisions from the *AWP* litigation. But Plaintiffs fail to acknowledge that those cases predate the amendments, which clarified that "[w]hile underlying fraudulent conduct … may constitute 'false statement[s]' for purposes of § 3729(a)(1)(B), such conduct does not in and of itself establish the 'false or fraudulent claim' required for liability under both §§ 3729(a)(1)(A) and (B).'" *United States ex rel. Booker v. Pfizer, Inc.*, 9 F.Supp.3d 34, 53 (D. Mass. 2014). Moreover, this is nothing like the *AWP* litigation. Here it is the government, not the defendants, that seeks to artificially manipulate the price actually paid by physicians in the real world. Worse still, Plaintiffs cannot even decide what "claim" they think was false. For § 3729(a)(1)(A), they say the "false or fraudulent claim" is the quarterly ASP submissions (which do not request a single cent); but when they turn to § 3729(a)(1)(B), the "claim" becomes the reimbursement requests submitted by ophthalmologists (which do not contain a single falsehood). That Janus-faced position is striking—not least because both positions are wrong on the merits.

Plaintiffs have also failed to plausibly allege that Regeneron acted with scienter. And their duplicative non-FCA claims all fail too. The Court should dismiss the complaints with prejudice.

ARGUMENT

I. Regeneron Complied With The ASP Statute And The Regulation.

A. Neither Statute Nor Regulation Requires Deducting Credit Card Processing Fees.

Under 42 U.S.C. § 1395w-3a(c)(3), ASP "shall include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement,

chargebacks, and rebates (other than rebates [elsewhere provided for in the Medicare Act]).” Conspicuously absent from that list is “reimbursing credit card processing fees,” or “reimbursing distributors for expenses actually incurred,” or anything similar. But that is all Plaintiffs allege that Regeneron did wrong. *See, e.g.*, Compl. ¶¶ 60, 103; Opp’n 16. Plaintiffs’ claims thus fail.

To try to avoid that straightforward and fatal conclusion under the statute, Plaintiffs point to the regulation, which they claim goes much further than the statute and requires manufacturers to include in ASP anything that (DOJ says) constitutes a price concession, even if it is not on the statutory list. Plaintiffs cannot so readily leave the statute behind. While Congress granted HHS (not DOJ) authority to add additional price concessions to the list, HHS has never exercised it, and instead has only parroted the statutory list and clarified what is *not* included—namely, BFSFs. That is critical. Even in the *Chevron* era, agencies received no deference when regulations merely parroted statutory language. *See, e.g.*, *Gonzales v. Oregon*, 546 U.S. 243, 257 (2006). Thus, DOJ is stuck with the list Congress enumerated (and HHS reproduced)—which does not include reimbursing transaction-processing fees actually incurred by distributors, or anything even close.

Plaintiffs disagree, arguing that “42 C.F.R. § 414.804(a)(2)(i) cannot reasonably be read to limit price concessions to the enumerated categories in § 414.804(a)(2)(i)(A)-(E).” Opp’n 15. In reality, however, that is the *only* reasonable reading of the regulation. The regulation begins by declaring that “a manufacturer must deduct price concessions” in calculating ASP; it then says that “[p]rice concessions include the following types of transactions and items,” listing the six types of price concessions Congress enumerated in the statute *and only those six*; and it ends by clarifying that “bona fide services fees are not considered price concessions.” 42 C.F.R. § 414.804(a)(2)(i)-(ii). Nowhere does the regulation expand Congress’ list or say that “*all* price concessions,

including *but not limited to* those in the statute," must be included in ASP. *Contra* Opp'n 15.

The ASP regulation could have said that. It could have said that manufacturers "must deduct *all* price concessions" (or "all transactions and items that result in the end-purchaser paying a lower price than the ordinary list price"). It could have said that "price concessions include" certain, specific transactions or items other than what is in the statute. Any of those would have indicated that HHS was exercising its delegated authority and requiring them to "include in [ASP] other price concessions" beyond the statutorily enumerated six. 42 U.S.C. § 1395w-3a(c)(3). But HHS did none of that; it just reproduced the statutory list while clarifying that bona fide service fees may be excluded even if they might resemble something on the list (e.g., a chargeback).

Plaintiffs nonetheless assert that the regulation's use of the word "include" serves to do implicitly what HHS plainly did not do explicitly—i.e., mandate that manufacturers must deduct *all* price concessions from ASP, even if they are not on the list Congress enumerated and HHS reiterated. Opp'n 14-15. But the government fails to cite any authority for the proposition that an agency can substantially expand a statutory list or avoid the *Gonzalez* anti-parroting principle by the simple expedient of using "include" in a regulation that otherwise reiterates statutorily enumerated categories, and we are aware of none. To be sure, "the word 'include' can signal that the list that follows is meant to be illustrative rather than exhaustive." *Samantar v. Yousuf*, 560 U.S. 305, 317 (2010). But "include" is also used interchangeably with "means," i.e., to define a term. *See, e.g.*, *United States v. Adams*, 40 F.4th 1162, 1169 (10th Cir. 2022) (holding that a "provision [that] states that the term *person* 'include[s] … every infant member of the species homo sapiens who is born alive'" does not extend beyond that phrase); *Adams v. Dole*, 927 F.2d 771, 777 (4th Cir. 1991) (holding that a statute's use of the word "including" to define "employer" "is not meant to be illustrative, but rather definitional"). Indeed, *the ASP statute* uses the term

"include" to exhaust the categories of price concessions that must be reflected in ASP absent subsequent regulatory action: Congress plainly limited what must be "include[d]" in ASP to the six enumerated types of price concessions. *See* 42 U.S.C. § 1395w-3a(c)(3) (ASP "shall include volume discounts, prompt pay discounts, cash discounts, free goods … , chargebacks, and rebates"). Tellingly, the statute separately authorized HHS to add "other price concessions," *id.*, but Congress did not think it was authorizing agency action simply by using the term "include."

Furthermore, there is absolutely zero indication that HHS (as opposed to DOJ, after the fact) thought that, simply by using the word "include," it was expanding the list of price concessions beyond what Congress enumerated in the statute and HHS reproduced in the regulation. Plaintiffs cite nothing in the accompanying Federal Register or in subsequent HHS pronouncements on ASP that even so much as hints that the agency thought it was expanding the list beyond what is in the statute. That is because there is nothing to cite. CMS did not invoke HHS' delegated authority to require manufacturers to deduct "other price concessions" beyond the ones in the statute *either* when it gave notice of the proposed regulation, *see* 71 Fed. Reg. 48,982, 49,082 (proposed Aug. 22, 2006), *or* when it published the final regulation, *see* 71 Fed. Reg. 69,624, 69,787 (Dec. 1, 2006). And that is the quintessential dog that did not bark: When the agency actually intends to use the authority Congress delegated to it in the Medicare Act, *it says so*, explicitly signposting its reliance on that authority. *See, e.g.*, 71 Fed. Reg. at 69,673; 70 Fed. Reg. 70,478, 70,479 (Nov. 21, 2005). Against that backdrop, it would defy both law and logic to hold that HHS dramatically increased the scope of what manufacturers must deduct from ASP *without telling anybody*. *Cf. Whitman v. Am. Trucking Ass'ns, Inc.*, 531 U.S. 457, 468 (2001) (laws "do[] not[] … hide elephants in mouseholes").

In a last-ditch effort, Plaintiffs contend that the BFSF carveout actually underscores that

HHS substantially (but implicitly) expanded the statutory list, because otherwise (they say) there would be no reason "to distinguish BFSFs" in the text. Opp'n 17. Nonsense. CMS was advising that BFSFs were excludable from ASP *even before* it adopted the regulation in December 2006. *See* Ex. A. That is because there are several good reasons to make clear that BFSFs need not be included in ASP—starting with trying to give the regulated community a modicum of guidance about what can be excluded in the difficult task of calculating ASP. In all events, clarifying regulations often do no more than clarify, and rarely, if ever, signal a substantial expansion of what must be *included* in the guise of clarifying what can be safely *excluded*. And the clarification that certain transactions that (unlike those here) could be covered by the statutory language were in fact excluded was sorely needed. Distributors often incur service fees when distributing products, and manufacturers often reimburse them *after the fact* in transactions that look like chargebacks or rebates (which are on the list). The BFSF carveout clarifies that ASP does not turn on whether a manufacturer reimburses distributors after they incur a service cost or pays them beforehand.

Plaintiffs' theory has no answer for CMS' actions with respect to "intentional overfill," which a relator contended functioned as a discount by effectively lowering the per-unit price of a drug by putting extra in each vial. *See United States ex rel. Westmoreland v. Amgen, Inc.*, 812 F.Supp.2d 39, 65 (D. Mass. 2011). In 2010, CMS "declin[ed] to consider overfill to be a discount for purposes of the ASP calculation." 75 Fed. Reg. 73,170, 73,468 (Nov. 29, 2010). If CMS thought that it had already required that all price concessions be included, as Plaintiffs claim it did, it surely would have just said *that*, and then carved out overfill from that earlier regulatory expansion. It did no such thing. Plaintiffs have no credible response to Judge Young's decision in *Westmoreland*, which held in no uncertain terms that even though "CMS did not explicitly reject the notion" that "overfill" could be considered a "free good" or "discount"—and thus a price

concession—"[CMS] recognized its authority to identify additional price concessions that must be accounted for in the ASP calculation" *and did not do so with respect to overfill*. 812 F.Supp.2d at 68 (citing 75 Fed. Reg. at 73,468). Judge Young thus rejected an interpretation of the regulation that would have required manufacturers to deduct all price concessions. This Court should too.

B. Reimbursing Credit Card Processing Fees Is Not A "Discount" Or A "Rebate."

Because HHS has not expanded the universe of "price concessions" that must be included in ASP, Plaintiffs' case rises and falls on whether reimbursing credit card processing fees qualifies as one of the six enumerated price concessions. But no matter how hard they try, Plaintiffs cannot jam a square peg into the statute's round holes. The complaint seemed to claim that reimbursing distributors for credit card processing fees was a species of "cash discount." *See* Compl. ¶¶ 75-76. Plaintiffs now jettison that theory, never mentioning it in their brief. That is wise, but it underscores the fundamental problem: The reason Plaintiffs cannot settle on a theory of how Regeneron's conduct supposedly violates the statute or regulation *is that it does not.*

Having abandoned their "cash discount" theory, Plaintiffs now half-heartedly argue that Regeneron effectively offered *physicians* a "rebate" by reimbursing *distributors* for the actual costs incurred in processing credit card transactions. *See* Opp'n 16. That is incoherent. Reimbursing *distributors* for expenses *they* incur is not remotely like giving *physicians* a rebate. Physicians receive nothing—from either distributors or Regeneron—for paying with plastic. And to the extent physicians receive rewards from credit card companies, that has nothing to do with Regeneron—and does not create FCA liability, as even Plaintiffs now concede. Opp'n 19.

As one federal District Judge recently put it, "'reimbursement' and 'rebate' mean different things." *Retina Assocs. of W. N.Y., P.C. v. McKesson Corp.*, 2023 WL 7326050, at *5 (W.D.N.Y. Nov. 7, 2023). The ordinary meaning of "rebate" is a retroactive discount that a seller gives to buyers in the form of a return of funds, usually in exchange for buyers doing something other than

simply buying the product. *See Rebate*, Black's Law Dictionary (11th ed. 2019) ("A return of part of a payment, serving as a discount or reduction."); *see also, e.g.*, 42 U.S.C. § 1786(b)(18) (so using "rebate"). That is not what Plaintiffs claim Regeneron did here. Again, all Plaintiffs accuse Regeneron of doing is *reimbursing distributors* for the costs the distributors actually incurred in processing credit card payments. Plaintiffs cannot credibly contend this is a "rebate," which is likely why they devote only a single, half-hearted sentence to the argument.

Nor, finally, is it a "subsidy," the label Plaintiffs newly ascribe to the reimbursements (after first trying "cash discount" and then briefly pivoting to "rebate"). Of course, it would make no difference even if it somehow *were* a "subsidy," as subsidies are obviously not on the list of price concessions that shall be included in ASP. It also makes sense that neither "subsidy" nor any synonym is on the list of price concessions; subsidies are typically granted by governments to promote something in the public interest but in need of assistance. In all events, Plaintiffs' belated effort to slap on the "subsidy" label fails for even more basic reasons. Paying a distributor back for an expense it actually incurred is not a subsidy; it is just a reimbursement of an actual, ordinary, and bona fide cost that distributors actually incur in the process of distribution.[1]

C. Reimbursing Credit Card Processing Fees Is Not A "Price Concession."

Finally, even if Regeneron somehow needed to include in ASP "price concessions" other than the ones Congress listed in the statute and CMS reiterated in the regulation, Plaintiffs' claims would still fail, because reimbursing distributors for transaction processing fees is simply not a "price concession." "The term ['price concession'] is not defined in the statute" or the HHS

[1] Indeed, Plaintiffs' theory is ultimately at war with itself. Even if Plaintiffs are correct that distributors in effect charged a higher price to credit card purchasers than cash purchasers (even though they really charged a single cash-or-credit price), this case still fails at the threshold, because all that would mean is that distributors charged a higher price for credit card purchases, and then discounted that price *by the amount of the credit card fees*—leading to the exact same ASP for those transactions, and thus zero dollars in additional expenditures out of the federal fisc.

regulation, "so 'we give the term its ordinary meaning.'" *Encino Motorcars, LLC v. Navarro*, 584 U.S. 79, 85 (2018) (quoting *Taniguchi v. Kan Pac. Saipan, Ltd.*, 566 U.S. 560, 566 (2012)). As Regeneron noted in its MTD (at 17), the ordinary meaning of "price concession" is a "reduction in price" from the listed price. *Concession*, Webster's Third New International Dictionary (2002). But all Regeneron did was ensure that all physicians *paid the same price* regardless of payment method. That is clear on the face of the complaint. *See, e.g.*, Compl. ¶ 2 (Regeneron "pa[ys]" distributors back for the cost of credit card processing so "doctors and retina practices that purchase[] Eylea c[an] use credit cards *at no additional cost*" (emphasis added)). Ensuring "no additional cost" is imposed is not giving a price concession or doing anything remotely nefarious; it is how most businesses operate every day when they allow consumers to pay with plastic.

Plaintiffs twist themselves into knots trying to obfuscate that reality, conflating the price that Regeneron initially charges distributors with the price distributors charge physicians. *See, e.g.*, Opp'n 16. But the documents Plaintiffs themselves attached to their complaint make crystal clear that, just like most merchants with most products, distributors charged physicians a single cash-or-credit price for EYLEA—just as Regeneron would have done if it sold EYLEA directly to ophthalmic practices rather than through distributors. *See, e.g.*, Compl. Ex. 5 at 26. Charging everyone the same price for a drug regardless of how they pay simply is not a price concession.

II. Credit Card Processing Fees Are Bona Fide Service Fees.

Plaintiffs' claims fail for yet another reason: Credit card processing fees are bona fide service fees, which "are not considered price concessions" even if they look like chargebacks or rebates (and thus may otherwise fit within the enumerated list). 42 C.F.R. § 414.804(a)(2)(ii). CMS defined BFSFs as "fees paid by a manufacturer to an entity, that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement,

and that are not passed on." *Id.* § 414.802. Remarkably, Plaintiffs do not deny that credit card processing fees satisfy each element. That should be the end of it.

Plaintiffs attempt to resist that result by arguing that the *real* "service" was not credit card processing, but "distributors not … charg[ing] more for credit card use." Opp'n 21. That is sophistry, not substantive argument—and it reads the BFSF regulation out of the C.F.R. Literally any BFSF could be reframed this way. Take shipping fees, which Plaintiffs concede are bona fide. It would be easy enough to recharacterize them as fees paid for "distributors not … charging more for [shipping]." And that would not change one whit the reality that reimbursed shipping fees are a prototypical BFSF. The same is true of reimbursed credit card processing fees.

This word game is no way to run a railroad, let alone for the United States and state governments to try to impose punitive fraud-based liability on one of their corporate citizens. Yet it is Plaintiffs' only move, as these reimbursed credit card processing fees are plainly BFSFs. Distributors do not perform credit card processing themselves; financial institutions do—just as they would if Regeneron sold EYLEA directly to doctors' offices rather than through specialty distributors. Distributors do not actually do the shipping, either; they hire third parties and use the distribution fees from Regeneron to pay for them. Plaintiffs have no theory for why shipping is any less a service *for Regeneron* than payment processing. Nor could they: Shipping and payment processing are both inevitable costs of doing business and important components of ensuring that EYLEA reaches physicians and ultimately consumers. Regeneron covers the cost of those services because it does not want them to be passed onto customers—just as it would if it sold directly. So if, as Plaintiffs concede, covering the cost of shipping does not give customers a "windfall," then the same must be true of covering the cost of credit card processing.

Plaintiffs suggest that credit card processing is different from shipping because the former

is not "necess[ary] to the process of distribution." Opp'n 22. That is debatable, but irrelevant, as 42 C.F.R. § 414.802 does not say that bona fide services must be "necessary" to be covered; there are six elements, and "necessity" is not one of them. To be sure, the preamble to the BFSF rule states that CMS "interpret[s] the[bona fide and on-behalf-of] elements of the [BFSF] definition to encompass any reasonably necessary or useful services of value to the manufacturer." 71 Fed. Reg. at 69,668. But reasonable necessity and utility are not synonyms—and payment processing is plainly a "useful service[]," given that distribution depends on payment. Indeed, that is presumably why shipping fees are conceded BFSFs, even though having a third party provide shipping is not strictly necessary. And some kind of payment processing is just as necessary as some kind of shipping. If manufacturers reimbursed distributors for incoming wire transfer fees, would HHS deem that as an excludable BFSF for a necessary service, or a suspect payment? It is anyone's guess, and yet the government seeks to impose punitive liability for guessing wrong.

In the end, the only difference between shipping charges and credit card fees is one that cannot possibly make a difference—the unique two-sided nature of credit card markets means that, unlike most shippers, credit card companies incentivize customers to use their plastic by offering a wide range of rewards and cashback programs. But so what? That is all beyond Regeneron's control, and the relevant statute and regulation say nothing about credit card companies (as opposed to manufacturers and distributors) making payments to physicians. Plaintiffs ultimately recognize all this by expressly disclaiming that the cashback and other rewards that credit card companies offer constitute price concessions or that Regeneron needs to factor in the amount of those rewards—as opposed to the different amounts that reflect credit card processing fees that distributors actually incurred and Regeneron actually reimbursed—into ASP. Opp'n 19.

One final point bears emphasis. This is not a case where a manufacturer has concocted a

novel or complicated scheme to distort its ASP so that it varies from the price physicians actually pay (as in the *AWP* litigation). If that were the case, it would at least be understandable that the government was trying to stretch statutory and regulatory language past the breaking point. But credit cards and credit card rewards programs are ubiquitous, as is the practice of allowing customers to pay with plastic without an upcharge. Indeed, credit cards are so ubiquitous that some merchants no longer accept cash. Kim Porter, *What To Do when Cash Isn't Accepted*, AARP (Jan. 11, 2023), https://perma.cc/PHJ8-HVC9. If Congress wants to address this widespread practice expressly, it is welcome to do so. But for the government to do nothing to clarify how to treat the reimbursement of ubiquitous fees that meet all regulatory criteria for bona fide service fees, and then turn around and seek punitive liability under the FCA, is beyond the pale.

III. Regeneron's Interpretation Was Plainly Reasonable.

This Court should definitively reject Plaintiffs' interpretations—but it does not need to in order to grant Regeneron's MTD; it need only hold that Regeneron's judgments in calculating ASP were not unreasonable. Regeneron did what HHS asked of it: It made reasonable assumptions in calculating ASP. And *not even Plaintiffs argue that Regeneron's conclusions were unreasonable.*

Plaintiffs instead argue that whether Regeneron's interpretation is reasonable presents a fact question that is not yet ripe, Opp'n 33, and Regeneron must first "establish[that] its current arguments are the interpretation it held at the time," Opp'n 36. That is doubly wrong. Whether a legal interpretation is reasonable is as *legal* as questions get, *see Ortiz v. Jordan*, 562 U.S. 180, 190 (2011), and thus ripe for a motion to dismiss. And *contra* Opp'n 36-37, nothing in *United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739 (2023), contradicts that. That makes sense, since "*Schutte* interpreted the FCA's scienter element, not its falsity element." *United States ex rel. Sheldon v. Forest Labs., LLC*, 2024 WL 3555116, at *31 n.26 (D. Md. July 23, 2024). And *Schutte* did not involve a regulation that demanded only reasonable judgments, such that an

objectively reasonable calculation is not false or fraudulent, let alone the basis for massive liability.

Plaintiffs are thus left arguing that Regeneron is "eli[ding] the Complaint's allegations." Opp'n 34. That is baffling. Plaintiffs' whole case boils down to the claim that Regeneron needed to include in EYLEA's ASP the cost of reimbursing distributors for credit card processing fees. Regeneron freely admits that, as a matter of fact, it did not do so. All Regeneron is saying is that, *as a matter of law*, (1) it did not need to, and (2) even if the Court disagrees, it is a sufficiently close question that not including the fees in ASP cannot be "false."

Plaintiffs next accuse Regeneron of "overstat[ing]" the First Circuit's decision in *United States ex rel. Jones v. Brigham & Women's Hospital*, 678 F.3d 72 (1st Cir. 2012). Opp'n 19-20. Plaintiffs miss the forest for the trees. To be sure, *Brigham & Women's* held that "a grant application [that] relied on falsified data" might still be false or fraudulent. Opp'n 20 (citing 678 F.3d at 88). That makes sense; no reasonable mind can approve of intentionally falsifying *facts*. But that is not what we are talking about here. Plaintiffs allege that Regeneron got the *law* wrong. And getting law reasonably wrong is precisely what the First Circuit was talking about in the critical passage Plaintiffs run away from. There are no two ways to understand the First Circuit's pronouncement that "statements as to conclusions about which reasonable minds may differ cannot be false." *Brigham & Women's*, 678 F.3d at 87 (citation omitted). That language closely tracks what other circuits have said in holding that certifying compliance based on a reasonable interpretation of a legal obligation cannot form the basis of FCA liability. *See, e.g.*, *United States ex rel. Yannacopoulos v. Gen. Dynamics*, 652 F.3d 818, 836-37 (7th Cir. 2011) (reasonable "'differences in interpretation growing out of a disputed legal question'" cannot "establish … falsity"); *United States v. AseraCare, Inc.*, 938 F.3d 1278, 1297-98 (11th Cir. 2019) ("mere difference of reasonable opinion" cannot "show objective falsity"). And it confirms that even if

this Court thinks Plaintiffs have the better reading of the statute and regulation, *but see supra*, Plaintiffs' claims still fail. *See, e.g.*, *Sheldon*, 2024 WL 3555116, at *32 (concluding as a matter of law that defendant did not violate statute because statute and related regulatory materials were ambiguous and thus did not set forth clear reporting obligations that could have "rendered [defendant's] price reports false").

Indeed, the result would be the same even putting *Brigham & Women's* aside. Plaintiffs simply disregard that, despite acknowledging the need for it, HHS has consistently refused to issue guidance identifying the types of service-fee arrangements that would qualify as presumptively bona fide (or not), explaining that it wants "to avoid inadvertently limiting the scope of what could constitute a bona fide service." 71 Fed. Reg. at 69,668; *accord* 72 Fed. Reg. 39,142, 39,184 (July 17, 2007). They also ignore CMS' advisement that "[m]anufacturers' reasonable assumptions[,] consistent with our requirements, guidance[,] and manufacturer's customary business practices[,] remain an important aspect of ASP reporting." 72 Fed. Reg. 66,222, 66,258 (Nov. 27, 2007).

Those omissions are not just galling, but telling. Regeneron pointed out in its MTD (at 29 n.6) that it knows of no case imposing FCA liability on a party that adopted a reasonable-but-erroneous interpretation of a regulatory obligation where the agency expressly invited parties to make reasonable judgments. Plaintiffs offer no reason why this Court should be the first in the (unlikely) event it disagrees with Regeneron's view of the statute and regulations. That makes the dismissal of this case straightforward, as no one can seriously argue that Regeneron's interpretation was unreasonable. Again, *even Plaintiffs do not make that argument*.

IV. Plaintiffs Have Not Plausibly Alleged Anything False Or Fraudulent About Any "Claims" Submitted To The Government.

Plaintiffs' theory of FCA liability rests principally (if not entirely) on decisions from nearly 20 years ago in the AWP context. *See* Opp'n 25-31. None of that goes very far today, however,

because *Congress subsequently amended the FCA in 2009*. Plaintiffs do not even acknowledge that the statute has changed, let alone explain how now-superseded *AWP* decisions could carry the day. Indeed, Plaintiffs go so far as to denigrate "Regeneron's argument"—i.e., that an actual false claim for payment is required for FCA liability under the current version of the statute—as "logical[ly] fallac[ious]." Opp'n 26. But Regeneron's argument just reflects the careful compromise Congress struck in the amendments (which Plaintiffs refuse to acknowledge).

In one sense, the amendments broadened the FCA, clarifying that a falsehood need not be "presented *to an officer or employee of the Government* before liability can attach," thereby creating FCA liability for subcontractors who submit falsehoods *to government contractors*. S. Rep. No. 111-10, at 10 (2009). But in another sense, the amendments narrowed the FCA by clarifying that, for liability to attach, there must be a falsehood in an actual "request or demand … for money or property." 31 U.S.C. § 3729(b)(2) (newly defining "claim").

That latter amendment explains why Plaintiffs' § 3729(a)(1)(A) theory fails. Post-2009, a chorus of courts have held that, in light of the amendment, there must be a falsehood in an actual "request or demand … for money or property" for FCA liability to attach. *See, e.g.*, *Booker*, 9 F.Supp.3d at 53; *United States ex rel. Rodwell v. Excelitas Techs., Corp.*, 2015 WL 3766866, at *4-5 (D. Mass. June 16, 2015); *United States ex rel. Grant v. United Airlines Inc.*, 912 F.3d 190, 196 (4th Cir. 2018). That is what Plaintiffs' § 3729(a)(1)(A) theory is missing. Plaintiffs contend that Regeneron's quarterly ASP submissions contain falsehoods triggering § 3729(a)(1)(A) liability. But as Regeneron has explained, *see* MTD 34, those quarterly ASP submissions do not "request or demand" any "money or property." That means they do not satisfy the FCA's definition of "claim." Any supposed falsehood in them is thus irrelevant and cannot serve as the basis for FCA liability.

Plaintiffs' § 3729(a)(1)(B) theory at least has the virtue of identifying an actual "claim" as

the FCA now defines that term: reimbursement requests submitted by ophthalmologists to CMS. Those obviously request federal dollars, which satisfies § 3729(b)(2)'s "claim" definition. But there is nothing false about those requests, so they cannot serve as the basis for FCA liability either.

Plaintiffs assert that the reimbursement requests are false because (they say) "[i]nflated claims based on false price reports are false or fraudulent." Opp'n 27-28. But Plaintiffs rely on outdated and *non-FCA* cases to support that assertion. FCA liability now requires an actual "claim" (i.e., a request for payment) that is actually false or fraudulent. What is more, just *one* of Plaintiffs' *AWP* cases arises under the current FCA—and it actually supports Regeneron, holding that the FCA "reaches [those] who 'knowingly *assist*[] in causing' the Government to pay *claims* grounded in fraud." *United States ex rel. Hueseman v. Pro. Compounding Ctrs. of Am., Inc.*, 2024 WL 2244818, at *4 (W.D. Tex. May 1, 2024) (emphases added). There must be something false about the "claim" itself—not about a manufacturer's pricing submissions to the government. Simply put, a false statement no longer "in and of itself establish[es] the 'false or fraudulent claim' required for liability." *Booker*, 9 F.Supp.3d at 53. "[A] necessary element is that an actual false claim was submitted to the government." *Rodwell*, 2015 WL 3766866, at *4. Plaintiffs have identified none.

It also bears emphasis that this case is nothing like the *AWP* cases, where manufacturers reported AWPs that were wildly inflated from the prices doctors actually paid. The dynamic here is the opposite—the government seeks to fault Regeneron for reporting ASPs that reflect the single price doctors actually paid, whether they paid with cash or plastic.

Plaintiffs argue that the CMS Form 1500 ophthalmologists submit is false because physicians must certify that the claim complies with "all *applicable* Medicare and/or Medicaid laws, regulations, and program instructions." Opp'n 28 (emphasis added). But neither the ASP statute nor the regulations apply to physicians; they apply to manufacturers. *See, e.g.*, 42 C.F.R.

§ 414.804(a)(7) (requiring *manufacturers* to certify compliance with the ASP statute and regulations). Plaintiffs try to bridge that gap by citing *Escobar*, but that case cannot bear the weight. To be sure, *Escobar* recognizes an "implied false certification theory" of FCA liability when a defendant itself "makes representations in submitting a claim but omits its [own] violations of statutory[or] regulatory[] … requirements." *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 186-87 (2016). But neither *Escobar* nor *any* case contemplates holding FCA defendants liable for representations made by another dealing only with the latter's legal compliance. *See United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 727 (1st Cir. 2007).

In the end, Plaintiffs cannot wish away *New York v. Amgen Inc.*, 652 F.3d 103 (1st Cir. 2011), or *Booker*—both of which hold that FCA plaintiffs cannot "use [allegedly] fraudulent conduct to avoid the need to show false claims," 9 F.Supp.3d at 53. *See* MTD 35-36 (collecting cases). *Contra* Opp'n 30, those cases did not turn on a simple failure to "connect an alleged fraud with a payment by the applicable government program." Instead, the failure to identify when the *defendant* "misrepresented compliance with a precondition of payment" meant that *there was no false claim*, and thus no liability under § 3729(a)(1)(B). *Amgen*, 652 F.3d at 111. Because that describes this case to a T, Plaintiffs' § 3729(a)(1)(B) claim fails once more.[2]

V. Plaintiffs Have Not Plausibly Alleged Scienter.

After spending three years investigating this matter—and forcing Regeneron to spend millions of dollars complying with investigatory demands—it is quite a tell that rather than citing testimony from its investigation, Plaintiffs spend multiple pages defending their right to benefit from every possible factual inference. In truth, Plaintiffs are hoping the Court will infer things

[2] Plaintiffs tack on a paragraph-long fraudulent-inducement theory drawn from D.C. and Eleventh Circuit caselaw. There are several problems with this theory—the most obvious being that it *does not appear in the complaint*. *See Fraser v. MBTA*, 544 F.Supp.3d 148, 165 n.12 (D. Mass. 2021).

that, despite a three-year investigation, Plaintiffs cannot allege.

Plaintiffs urge the Court to infer scienter by claiming that Regeneron "understood the statutory and regulatory ASP reporting regime with enough clarity to engage in substantial internal discussion" and "solicit a third-party consultant" regarding "whether the credit card subsidies were reportable price concessions or alternatively, BFSFs." Opp'n 32. But pleading that a company "engage[s] in substantial internal discussion" and hires help where the regulator *steadfastly refuses to provide guidance* is not a plausible allegation that the company knowingly or recklessly violated the FCA. HHS has acknowledged not only that the BFSF issue is the opposite of clear, but that interpreting the statute and regulations demands a welter of assumptions. Plaintiffs ask the Court to draw the manifestly unreasonable inference that Regeneron engaged in substantial discussion and hired Deloitte even though it *already knew what the law required*, and that when Deloitte told it something it did not want to hear, it flouted the recommendation and prepared the 27-page 2016 Reasonable Assumptions document attached to the complaint as a "self-serving" sham. Allowing Plaintiffs to survive a motion to dismiss on that theory would strain the plausibility standard past its breaking point—especially when the complaint stops short of pleading any one individual's knowledge. *See United States v. Regeneron Pharms., Inc.*, 2023 WL 7016900, at *14 n.19 (D. Mass. Oct. 25, 2023) ("'collective knowledge' doctrine does not apply" in FCA cases).[3]

VI. Plaintiffs' State-Law Claims Fail For All The Same Reasons.

Plaintiffs concede that dismissal under the federal FCA merits dismissal under the analogous statutes of Colorado, Georgia, Michigan, North Carolina, and Washington. Opp'n 38.

Plaintiffs assert, however, that "[u]nlike the FCA," the Texas Medicaid Fraud Prevention

[3] This is not a case where plaintiffs need discovery to prove their claims. DOJ spent three years investigating, obtained hundreds of thousands of pages of Regeneron documents, and interviewed a litany of current and former company employees as well as the relevant Deloitte consultants (and notably failed to cite any testimony from these witnesses).

Act ("TMFPA") does not "require presentment of a false claim to incur liability." Opp'n 39. But Plaintiffs do not point to a single decision holding that the TMFPA does not require the presentment of a false claim. And while they imply that the TMFPA is broader than the FCA in other respects, Opp'n 39-40, they do not identify any specific arguments on that point—thus forfeiting them.[4]

VII. The Court Should Dismiss Plaintiffs' Duplicative Unjust Enrichment Claims.

Plaintiffs claim that courts in this Circuit "routinely" decline to dismiss unjust enrichment claims pled in the alternative. Opp'n 38. That is wrong. Plaintiffs muster only one case in this Circuit permitting an unjust enrichment claim pled in the alternative to survive—and that 20-year-old case simply decided not to "resolve" the issue "at this stage." *Massachusetts v. Mylan Labs.*, 357 F.Supp.2d 314, 324 (D. Mass. 2005). On the flip side, a bevy of recent decisions from this District dismissed unjust enrichment claims pled in the alternative because "an adequate remedy at law is available" through the FCA. *United States ex rel. Martino-Fleming v. S. Bay Mental Health Ctrs.*, 540 F.Supp.3d 103, 132-33 (D. Mass. 2021); *see also, e.g.*, *United States v. Regeneron Pharms., Inc.*, 2023 WL 6296393, at *14 (D. Mass. Sept. 27, 2023); *United States v. Teva Pharms. USA, Inc.*, 560 F.Supp.3d 412, 423-24 (D. Mass. 2021); *United States v. Buckley*, 2005 WL 164287, at *1 (D. Mass. Jan. 25, 2005). The Court should do so again here.

CONCLUSION

Plaintiffs' claims should be dismissed with prejudice.

[4] Plaintiffs are also wrong. The TMFPA "prohibit[s] substantially the same conduct" as the FCA. *United States v. Planned Parenthood Gulf Coast, Inc.*, 21 F.Supp.3d 825, 830-31 (S.D. Tex. 2014).

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that this document was filed through the Court's CM/ECF system on October 4, 2024, and will be sent electronically to the registered participants as identified on the Notice of Electronic Filing.

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